

Appl. No. : 09/632,074
Filed : August 2, 2000

REMARKS

The Specification and Claims have been amended to more clearly recite the invention as claimed. The Specification and Drawings were amended as requested by the Examiner to refer to Figures 5A and 5B with upper case letters. Claim 1 was amended in line with Restriction Requirement of August 12, 2003 to specify that the modulation is a reduction. Claims 10, 13-16, and 19 were withdrawn as being drawn to a non-elected invention. As a result of the amendment, Claims 1-9, 17 and 18 are presented for further examination. The changes made to the Specification and Claims by the current amendment, including ~~deletions~~ and additions, are shown herein with deletions designated with a strikethrough and additions underlined. No new matter has been added herewith.

Claim Objections

Claim 1 and its dependencies have been amended in line with the Restriction Requirement to specify that the modulation is a reduction. In view of this amendment, Applicants respectfully request that the claim objections be removed.

Rejection under 35 U.S.C. §102(b)

The Examiner has rejected claims 1-9 and 17-18 as anticipated by Ke et al. (U.S. Patent No. 6,352,970).

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

The claimed invention is "A method of modulating **[inhibiting] bone resorption** in an animal, said method comprising administering to said animal an effective amount of a leptin..." (bracketed word and emphasis added).

The Examiner states that Ke et al. anticipates the claimed invention because "[t]he formation of bone is a combination of bone resorption and bone formation, therefore, if the net effect is to prevent bone loss, then resorption would necessarily be inhibited". Applicants respectfully submit that this is incorrect. All that is required is that bone formation exceeds bone resorption. For example, a therapy that actually increased bone resorption, but increased

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AMENDMENTS TO THE DRAWINGS

Please amend Figures 4 and 5 as shown in the corrected drawings in Appendix A.

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formation to a greater extent, would “prevent bone loss”. Thus, Ke et al. does not anticipate the claimed invention because Ke et al. does not teach each and every claim element because Ke et al. does not teach the use of Leptin to **inhibit bone resorption**.

Rejection under 35 U.S.C. §103(a)

The Examiner has rejected claims 1-9 and 17-18 as unpatentable in view of Liu et al. (American Society for Bone and Mineral Research, 19th Annual Meeting, Sept. 10-14, 1997, Cincinnati Ohio).

The law is clear that three basic criteria must be met to establish a *prima facie* case of obviousness: (MPEP ¶2143):

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references, when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure (*In re Vaack*, 947 F.2d 488, 20 USPQ2d 1440 (Fed. Cir. 1991)).

The claimed invention is “A method of modulating **[inhibiting] bone resorption** in an animal, said method comprising administering to said animal an effective amount of a leptin...” (bracketed word and emphasis added).

Liu et al. found that leptin stimulated cortical bone formation in ob/ob (ie. Leptin deficient) mice and suggested that leptin could be used to treat bone loss associated with diabetes and/or glucocorticoid excess. This implies that the mechanism would be increased bone formation not decreased bone resorption.

Lie et al. states that osteoclast numbers were not affected and there is no data to suggest that leptin inhibits bone resorption. The Examiner alleges that “...one of ordinary skill in the art would be motivated to administer leptin in order to stimulate bone resorption” (emphasis added). This implies that bone resorption would increase when bone formation is increased due to “coupling”. However, technically, as mentioned above in the anticipation rejection, this does not make sense.

The claimed invention is a method of reducing bone resorption by administering Leptin. Liu et al. presents a method of stimulating bone formation. Thus, Liu et al. does not teach all of

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the claim limitations because Liu et al. does not teach inhibition of bone resorption and Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

Conclusion

Should there be any questions related to the above-identified patent application, the Examiner is respectfully requested to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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